NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, *et al.*, *ex rel.* JESSICA PENELOW and CHRISTINE BRANCACCIO, Plaintiffs, v. JANSSEN PRODUCTS, LP, Defendant.	Civil Action No. 12-7758 (ZNQ) (LHG) **MEMORANDUM OPINION**

QURAISHI, District Judge

This matter comes before the Court upon a Motion for Summary Judgment (the "Motion") filed by Janssen Products, LP ("Janssen"). (ECF No. 187.) Janssen submitted a Brief in Support of the Motion. ("Moving Br.," ECF No. 187-1.) Relators Jessica Penelow and Christine Brancaccio (collectively, "Relators") opposed the Motion, ("Opp'n Br.," ECF No. 287), to which Defendant replied, ("Reply Br.," ECF No. 242). The Court carefully considered the parties' submissions and decided the matter without oral argument pursuant to Federal Rule of Civil Procedure 78 and Local Civil Rule 78.1. For the reasons set forth below, the Court will deny Janssen's Motion.

I. BACKGROUND

Relators filed the instant action on behalf of the federal government, twenty-six states, and the District of Columbia, alleging fifty-six counts under the Federal False Claims Act ("FCA"), the Federal Anti-Kickback Statute ("AKS"), and the false claims acts of various states. ("Second

Am. Compl." at 1–2, ECF No. 90.) The claims arise from Janssen's purported kickback scheme and off-label ("OL") promotions of two HIV/AIDS drugs: Prezista and Intelence. *Id.*

II. UNDISPUTED MATERIAL FACTS

On December 18, 2012, Relators Penelow, a former Janssen employee, and Brancaccio, a current Janssen employee, filed under seal this *qui tam* action against Janssen and its corporate parent, Johnson & Johnson. (Def's Statement of Material Facts ("DSMF") ¶ 1, ECF No. 187-2; ECF No. 1.) The United States and several states declined to intervene in this action. (*Id.* ¶¶ 3, 6.) On May 31, 2017, the Court dismissed all claims against Johnson & Johnson and all claims brought by Relators on behalf of the State of Maryland. (*Id.* ¶ 7; ECF No. 86.)

On June 30, 2017, Relators filed their Second Amended Complaint, the operative complaint in this case. (*Id.* ¶ 10.) Relators and Janssen engaged in approximately three years of discovery in this matter. (*Id.* ¶ 11.) During that time, almost two million pages of documents were produced and seventeen current and former Janssen employees were deposed, including account managers, sales training managers, and sales representatives. (*Id.* ¶¶ 12, 14.) The owner of the third-party agency that conducted return on investment analyses was deposed. (*Id.* ¶ 15.) Furthermore, four proposed Janssen expert witnesses issued reports discussing Medicare Part D, causation and damages, HIV, and compliance. (*Id.* ¶ 17.) In turn, seven proposed expert witnesses issued reports on behalf of Relators concerning similar topics. (*Id.* ¶ 18.)

The HIV drugs at issue are antiretroviral medications that stop the HIV virus from replicating, which prevents HIV progression, opportunistic infections, and death. (*Id.* ¶¶ 20, 33.) Twenty-eight FDA-approved antiretroviral medications were available during the nine-year period (2006 to 2014) over which Relators allege Janssen improperly marketed Prezista and Intelence. (*Id.* ¶ 21.) These antiretroviral medications are divided into six different classes based on how the

medication disrupts HIV replication. (*Id.*) Doctors often prescribe "cocktails" of drugs consisting of two or more antiretrovirals from different classes to interfere with viral replication at multiple points. (*Id.* ¶ 22.)

When determining which antiretroviral medications to prescribe, the doctor's primary goal is to stop the patient's HIV from replicating. (*Id.* ¶ 24.) Doctors also strive to minimize side effects to the patient, ensure patient adherence to the prescribed therapy, enhance the patient's quality of life, and co-manage the patient's other chronic diseases. (*Id.* ¶ 26.) Therefore, HIV treatment requires individualized treatment because a regimen that is appropriate for one patient may be inappropriate for another. (*Id.* ¶ 23.) Before selecting a treatment regimen, doctors use blood tests to determine which regimen will be most effective, monitor efficacy of such treatment, and look for potential treatment side effects (including lipid abnormalities).[1] (*Id.* ¶¶ 27–28.) In addition, doctors consider numerous other factors in choosing the combination of antiretroviral medications to prescribe, including consensus-based treatment guidelines, patient medical history and characteristics, discussions from ongoing clinical trials, academic conferences, personal clinical experience, pharmaceutical promotion, and many other factors.[2] (*Id.* ¶ 29.)

The Department of Health and Human Services ("HHS") publishes consensus-based HIV treatment guidelines that "reflect the federal government's position on the standard of care for the use of HIV medications as it evolved over time, based on an expert panel's independent evaluation of reliable scientific research." (*Id.* ¶ 41.) The HHS guidelines are generally updated multiple

[1] Relators and Janssen agree that the viral load (amount of HIV virus in patient's bloodstream), CD4 count (the number of CD4 T-cells, or white blood cells), and viral genotype (the drug resistance-associated mutations) are taken into consideration when selecting an appropriate HIV treatment regimen. (*Id.* ¶ 27; ECF No. 287 at 7–8.) However, the parties disagree on whether physicians *always* consider the viral genotype. (DSMF ¶ 27.) The parties also disagree on the type of tests used to monitor the treatment and the frequency at which physicians run these tests. (*Id.* ¶ 28; ECF No. 287 at 7–8.)

[2] Relators dispute whether physicians consider all these factors every time they choose a particular combination of antiretroviral medications and that these factors represent an exhaustive list of what doctors consider in their decision-making process. (ECF No. 287 at 8.)

times each year to incorporate, among other things, peer-reviewed journals and data presented at major conferences. (*Id.* ¶ 42.)

Medicare Part D ("Part D") provides prescription drug coverage for the elderly and people with certain disabilities. (*Id.* ¶ 50.) It helps cover the costs of "covered Part D drugs," which are FDA-approved medications prescribed for a "medically accepted indication." (*Id.* ¶ 51.) Under the Part D statute, antiretroviral medications are designated as a "protected class of drugs," and the government requires Part D plans to cover "all or substantially all" FDA-approved antiretroviral medications in order "to mitigate the risks and complications associated with an interruption of therapy for . . . vulnerable populations." (*Id.* ¶ 53.) The Center for Medicare & Medicaid Services ("CMS") takes the position that for "HIV/AIDS drugs, utilization management tools such as prior authorization . . . are generally not employed in widely used, best practice formulary models." (*Id.* ¶ 54.)

Medicaid provides healthcare coverage for low-income people. (*Id.* ¶ 55.) It is funded jointly by the federal government and states, with the federal government contributing approximately 50% to 83% of the funding and states contributing the remainder. (*Id.* ¶ 56.) The federal government's share of a state's Medicaid expenditures is called federal financial participation ("FFP"). (*Id.* ¶ 57.) Although the federal government oversees Medicaid, the program is administered on a state-by-state basis, and states have discretion to customize their plans. (*Id.* ¶ 57.) The federal government permits state Medicaid programs to cover any drug that meets the regulatory definition of a "prescribed drug." (*Id.* ¶ 59.) "Prescribed drugs" are "substances prescribed for the cure, mitigation, or prevention of disease, or for health maintenance" by a doctor and dispensed by a pharmacist. (*Id.* ¶ 60.) Thus, a prescribed drug covered by a state Medicaid program is eligible for federal reimbursement. (*Id.* ¶ 61.)

States, however, may exclude or otherwise restrict coverage if a drug's "prescribed use is not for a medically accepted indication." (*Id.* ¶ 62.) Separately, states create and administer their own AIDS Drugs Assistance Programs ("ADAPs") programs through federal block grants that fund "core medical services" for HIV patients, including HIV medications. (*Id.* ¶ 64.) At a minimum, state ADAPs must cover "at least one drug from each class of HIV antiretroviral medications" but otherwise "have significant flexibility in how they administer their ADAPs" and are "given the authority to determine the specific FDA-approved drugs to cover." (*Id.* ¶ 66.) Ultimately, state ADAP programs serve as "payor of last resort" to improve the availability of and access to care for uninsured or under-insured HIV patients, and they fund HIV treatment when no other resources are available to them. (*Id.* ¶ 67.)

Prezista and Intelence—both manufactured, marketed, and sold by Janssen—are antiretroviral medications that are approved by the FDA to treat HIV. (*Id.* ¶ 32.) The FDA approved Prezista, a protease inhibitor, for treatment-experienced patients in June 2006. (*Id.* ¶ 33.) Prezista was later approved for treatment-naïve patients in October 2008. (*Id.* ¶ 34.) In January 2008, the FDA approved Intelence, a non-nucleoside reverse transcriptase inhibitor, for twice-daily use (two tablets, twice a day) and for treatment-experienced patients.[3] (*Id.* ¶ 37.)

Janssen promoted Prezista and Intelence to physicians through sales calls and speaker programs (the "Speaker Programs"). (*Id.* ¶ 38.) During sales calls, Janssen sales representatives spoke to doctors about the benefits of Prezista and Intelence for HIV patients. (*Id.* ¶ 39.) During the Speaker Programs, physicians educated other physicians about Prezista and Intelence. (*Id.* ¶ 40.)

[3] "Protease inhibitor" and "non-nucleoside reverse transcriptase inhibitor" refer to two distinct classes of antiretroviral medications used to treat HIV/AIDS.

III. STATEMENT OF DISPUTED FACTS

There are several major disputes between the parties. They disagree about the characterization of the FDA labels for Prezista and Intelence. They also disagree about the drugs' efficacy and the characterization of the HHS treatment guidelines. Notably, the parties disagree on the factors physicians consider when prescribing antiretroviral medications. With respect to the Speaker Programs, they dispute material facts concerning compliance issues. They also dispute material facts concerning remuneration for the physician speakers and material facts surrounding Janssen's attempts to determine the efficacy of Speaker Programs by conducting return on investment analyses.

IV. PARTIES' ARGUMENTS

A. Defendant's Motion for Summary Judgment

1. FCA Claims

Janssen argues that this Court should grant summary judgment as to the FCA claims ("Promotional Claims") because Relators have insufficient evidence to prove the following: (1) "that any claim submitted for a Prezista prescription for an HIV patient with lipid conditions was unreasonable and unnecessary and, therefore, *false*"; (2) "that any of Janssen's four alleged promotional messages *caused* a doctor to write a Prezista or Intelence prescription for any HIV patient"; and (3) "that any of Janssen's four alleged promotional messages were *material* to any decision by the government to pay for a Prezista or Intelence prescription." (Moving Br. at 2–4, 12–22.) Janssen asserts that summary judgment must be granted if Relators fail to prove *any one* of the FCA elements. (*Id.* at 12–13.)

First, although Relators' claims involve four OL promotional messages concerning Prezista and Intelence, Janssen only argues that Relators have insufficient evidence to prove falsity

as to their claims based on the promotion of Prezista as "lipid friendly" or "lipid neutral." (*Id.* at 13.) Janssen argues that Relators have insufficient evidence from which a jury could conclude that a Prezista prescription written for an HIV patient with lipid conditions was unreasonable and unnecessary because Relators failed to meet the second part of the "reasonable and necessary" analysis under *United States ex rel. Petratos v. Genentech*, 855 F.3d 481, 488 (3d Cir. 2017). (*Id.* at 14.) More specifically, Janssen argues that Relators presented no evidence that "it was unreasonable and unnecessary for the 'individual doctor' to prescribe Prezista to the 'individual patient' based on the particular 'medical circumstance of the individual case.'" (*Id.* at 14–15.) On a "macro, policy level" under *Petratos*, Janssen also argues that Prezista can be considered reasonable and necessary for an HIV patient with lipid conditions because the FDA approved Prezista as a safe and effective HIV treatment and the label for Prezista does not include any warnings about lipids or prescribing limitations for patients with lipid conditions. (*Id.* at 15.)

Second, Janssen argues "Relators have insufficient evidence to prove that any of Janssen's four alleged promotional messages caused a doctor to write a Prezista or Intelence prescription for a government-insured HIV patient." (*Id.* at 16.) In other words, Relators have no evidence that Janssen's OL promotion of Prezista and Intelence was a substantial factor in causing physicians to prescribe these medications for HIV patients. (*Id.*) Janssen claims that Relators obtained no patient-specific evidence, which would have "shed light on why particular doctors chose to prescribe Prezista or Intelence for particular HIV patients." (*Id.* at 17.) Given the complexity of a physician's decision-making process when treating HIV patients, Janssen argues that it is impossible for Relators to prove that the alleged OL promotional messages caused doctors to prescribe Prezista and Intelence without patient-specific evidence. (*Id.* at 17–18.) In addition, to the extent Relators rely on expert reports to establish causation, Janssen argues that the reports of Israel Shaked, Aaron Glatt, and George Sillup are inadmissible. (*Id.* at 18.) Also, Janssen distinguishes this matter from *United States ex rel. Brown*

v. Celgene Corp., 226 F. Supp. 3d 1032, 1037 (C.D. Cal. 2016), where Janssen claims "the circumstances made it reasonable to conclude that the [OL] use was caused by the improper promotion." (*Id.*)

Third, Janssen argues that "Relators have insufficient evidence to prove that any of Janssen's four alleged promotional messages were material to the government's decision to reimburse a Prezista or Intelence prescription." (*Id.*) Janssen contends Relators must show that knowing about Janssen's alleged OL promotion would have affected the government's payment decision. (*Id.* at 19.) In other words, Relators would have to show that "the government's decision to pay would have been different if the government had known about Janssen's alleged improper promotion." (*Id.* at 22.) Janssen maintains that Relators have "no evidence that Janssen's alleged promotional practices were material to any government decision." (*Id.* at 21–22.)

2. AKS Claims

As for the AKS claims ("Speaker Claims"), Janssen argues the Court should grant its motion for summary judgment for three reasons. First, "Relators do not have sufficient evidence to demonstrate that Janssen paid doctors who spoke at speaker programs in order to induce them to prescribe more Prezista or Intelence." (*Id.* at 22.) Like in *Celgene*, Janssen notes that the Speaker Programs here were organized by third-party vendors, the speakers were paid a flat fee per event, and the compensation was comparable to that provided by other drug companies. (*Id.* at 24.) Janssen argues that the burden shifts to Relators to identify sufficient evidence from which a reasonable jury could nonetheless conclude that Janssen paid speakers to induce them to prescribe more Prezista and Intelence—not just to compensate them for providing a valuable and lawful service. (*Id.*) To prove intent, Janssen claims that Relators will likely rely on the testimony from a handful of former Janssen employees who were not involved with the design and implementation of the Speaker Programs. (*Id.*) Janssen also notes that Relators will likely rely on the inadmissible testimony that Virginia Evans

intends to offer, which they claim is a legal conclusion. (*Id.*) Therefore, Janssen argues that none of the testimony Relators have will be a sufficient basis for a jury to conclude Janssen acted with the requisite intent to bribe doctors. (*Id.*)

Second, Janssen also claims Relators will likely "highlight evidence suggesting that experience prescribing Prezista and Intelence was a factor that Janssen considered in choosing doctors to be speakers." (*Id.* at 25.) However, Janssen argues that it considered many factors when selecting physicians for the Speaker Programs. (*Id.*) Third, Janssen claims that Relators will likely rely on two cases[4] from the Southern District of New York where "the courts denied the pharmaceutical companies' summary judgment motions on claims based on speaker programs." (*Id.*) Janssen explains, however, that one of those cases involved extensive evidence that the company specifically analyzed speaker prescription volume to determine whether the honoraria payments increased the speakers' prescriptions. (*Id.* at 25–26.) Here, Janssen argues that it only analyzed the promotional effectiveness of the Speaker Programs by analyzing whether the *attendees* prescribed more Prezista and Intelence after attending the Speaker Programs. (*Id.* at 26.) As for the other case, Janssen emphasizes that "Relators do not have any evidence that Janssen conducted speaker programs in inappropriate locations, that it regularly or significantly exceeded its food and beverage cap, or that it offered doctors any improper trips or entertainment." (*Id.* at 27.) To the extent Relators may suggest Janssen conducted too many Speaker Programs or should have had more attendees at the programs, Janssen argues that "companies do not violate the AKS by making business decisions that may not be the most efficient." (*Id.*)

[4] See *United States ex rel. Arnstein v. Teva Pharm. USA, Inc.*, Civ. No. 13-3702, 2019 WL 1245656 (S.D.N.Y. Feb. 27, 2019); Order Denying Motion for Summary Judgment, *United States ex rel. Bilotta v. Novartis Pharm. Corp.*, Civ. No. l l-71 (S.D.N.Y. Mar. 31 , 2019) (ECF No. 296) (opinion never issued because of settlement).

B. Relators' Opposition

Relators argue that Janssen misstates the applicable legal standard for falsity, causation, and materiality under the FCA. (Opp'n Br. at 21.) They argue that summary judgment should be denied because they obtained abundant evidence from which a reasonable jury could conclude that each of the FCA elements has been satisfied. (*Id.*)

First, Relators argue they have ample evidence to establish that Prezista claims for patients with lipid issues were false under the FCA. (*Id.* at 32.) They contend the "evidence shows that as a result of Janssen's false and misleading marketing, claims were submitted to the government for prescriptions for patients with lipid problems." (*Id.* at 33.) They argue that the claims were ineligible for reimbursement by the Government because they were medically unreasonable and unnecessary. Relators maintain that "Prezista was generally not appropriate for patients with lipid problems and there was an alternative drug from a different manufacturer that did not pose lipid concerns." (*Id.*) In addition, "Relators' evidence supports an express false certification theory by showing that Janssen caused pharmacies to make false certifications that claims submitted to the government for Prezista for patients with lipid issues complied with the law . . . ." (*Id.* at 40.) Relators have "evidence showing that Janssen's illegal marketing caused pharmacies to falsely certify compliance with the law when submitting medically unnecessary claims for Prezista for patients with lipid problems." (*Id.* at 40–41.)

Second, Relators argue there is abundant evidence that Janssen's conduct was a substantial factor in causing physicians to prescribe Prezista and Intelence OL and that it was foreseeable false claims would result. (*Id.*) They argue that the "vast body of evidence adduced . . . demonstrates the top-down, widespread, and coordinated illegal promotional efforts by Janssen to boost sales of Prezista and Intelence." (*Id.* at 24.) Relators identify evidence that Janssen trained and instructed

its entire sales force to promote Prezista and Intelence OL. (*Id.* at 25–26, 27.) In addition, Relators point to evidence that Janssen's OL marketing campaign extended to its Speaker Programs because Janssen also promoted its OL messages through the physician-speakers. (*Id.* at 27.) Relators contend that "evidence of direct causation at a physician-by-physician or claim-by-claim level is not required to satisfy the substantial factor test in FCA cases." (*Id.* at 22, 31–32.) They also argue that a physician's independent prescribing decision does not break the causal chain. (*Id.* at 30–31.)

Third, Relators argue the Court should deny summary judgment "because the evidence establishes a triable issue of fact from which a jury could conclude that Janssen's false and OL marketing of Prezista and Intelence could have impacted the government's reimbursement of the drugs." (*Id.* at 41.) They argue that Janssen relies on an erroneous standard for FCA liability and that "the proper test for determining materiality in FCA cases is whether the conduct at issue has 'a natural tendency to influence, or [is] capable of influencing, the payment or receipt of money or property.'" (*Id.* at 43–44.) Relators contend they are able to satisfy that materiality element because: (1) the government conditions payment on whether prescriptions are for medically accepted indications or are reasonable and necessary; (2) the government reimburses prescriptions that are OL or unreasonable and unnecessary goes to the "essence of the bargain"; (3) the government devotes significant efforts to combat OL marketing; and (4) Janssen knew the government devotes significant efforts to fighting OL marketing. (*Id.* at 44–49.)

Contrary to Janssen's arguments concerning the "Speaker Claims," Relators contend they have extensive evidence that Janssen used its nationwide Speaker Programs as a means to pay physicians to induce or reward their prescriptions of Prezista and Intelence. (*Id.* at 12.) They argue that Janssen focuses on limited evidence that is in dispute, which they claim is insufficient

to warrant summary judgment. (*Id.* at 17–20.) Relators emphasize that they do not need to prove the *sole* reason Janssen paid speakers was to induce them to prescribe or reward them for prescribing Prezista and Intelence. (*Id.* at 10.) Instead, Relators maintain that "payments to physicians violate the AKS if even 'one purpose' of the payments was to induce or reward the speakers," and Relators claim they have amassed substantial and compelling evidence that at least one purpose of Janssen's payments to speaker physicians was unlawful. (*Id.* at 10–11.) Relators point to sworn deposition testimony of seven current and former Janssen employees who testified that the Speaker Programs focused, in significant part, on inducing and rewarding prescriptions. (*Id.*) In addition, Relators highlight that Janssen paid hundreds of physicians a significant amount of money to give thousands of speeches over the relevant nine-year period. (*Id.* at 12–13.) "Janssen also paid [physicians] to attend training sessions and paid for hotels, meals, and travel expenses, making these events akin to paid vacations." (*Id.* at 13.) "Many speeches were held at inappropriate venues, including thousands at high-end restaurants." (*Id.*) Relators point to expert opinions that support a finding of unlawful inducement or reward. (*Id.*) They also note the existence of a considerable amount of circumstantial evidence in the form of testimony, documents, and data from which an unlawful purpose can be reasonably inferred. (*Id.*)

Moreover, Relators argue that "[o]ther factors considered by courts and the government as indicia of intent to violate the AKS are also well supported in the record." (*Id.* at 14.) They explain that Janssen tracked the prescriptions of the paid speakers *and* all attendees (some of whom were paid speakers as well) to monitor the return on investment of the Speaker Programs. (*Id.*) There is evidence that hundreds of physicians attended the same speech multiple times, and "the speeches were highly repetitive in nature and fairly rudimentary for the doctors attending." (*Id.* at 14–15.) Relators also point to evidence that the information presented during the Speaker Programs was

incomplete, inaccurate, and misleading and that the OL information about Prezista and Intelence was regularly presented by the highest paid speakers. (*Id.* at 15.) According to Relators, its expert economist will show that speakers continued to prescribe Prezista and Intelence once they started getting paid for speeches and that "speakers were more likely than non-speakers to prescribe Prezista and Intelence." (*Id.* at 15–16.) Additionally, the evidence will establish that Janssen's compliance department had little oversight over the Speaker Programs; instead, the Speaker Programs were controlled by Janssen's sale representatives (who were incentivized to increase sales) and its marketing department. (*Id.* at 16–17.)

C. Defendant's Reply

On reply, Janssen reiterates that Relators have no evidence the Government was defrauded when it paid for HIV medications for HIV patients. (Reply Br. at 1.) It contends Relators have no evidence that: (1) "Prezista prescriptions for HIV patients with lipid conditions falsely certified eligibility for reimbursement"; (2) "Janssen's purported promotion was a substantial factor in any prescribing decision"; and (3) Janssen's purported promotion was material to the government programs. (*Id.* at 1–9.) With respect to the AKS claims, Janssen argues that "Relators have no admissible evidence that one purpose of Janssen's speaker bureaus was to bribe doctors." (*Id.* at 9.)

V. JURISDICTION

The Court exercises subject matter jurisdiction under 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a) and (b). Venue is appropriate under 31 U.S.C. § 3732(a) because Janssen transacts business in this judicial district.

VI. LEGAL STANDARD

A "court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A material fact raises a "genuine" dispute "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Williams v. Borough of W. Chester*, 891 F.2d 458, 459 (3d Cir. 1989) (quoting *Anderson*, 477 U.S. at 248).

"In evaluating the evidence, the Court must consider all facts and their logical inferences in the light most favorable to the non-moving party." *Rhodes v. Marix Servicing, LLC*, 302 F. Supp. 3d 656, 661 (D.N.J. 2018) (citing *Curley v. Klem*, 298 F.3d 271, 276–77 (3d Cir. 2002)). "While the moving party bears the initial burden of proving an absence of a genuine dispute of material fact, meeting this obligation shifts the burden to the non-moving party to 'set forth specific facts showing that there is a genuine [dispute] for trial.'" *Id.* (quoting *Anderson*, 477 U.S. at 250). "Unsupported allegations, subjective beliefs, or argument alone . . . cannot forestall summary judgment." *Read v. Profeta*, 397 F. Supp. 3d 597, 625 (D.N.J. 2019). "Thus, if the nonmoving party fails 'to make a showing sufficient to establish the existence of an element essential to that party's case[,] . . . there can be no genuine issue of material fact.'" *Id.* (quoting *Katz v. Aetna Cas. & Sur. Co.*, 972 F.2d 53, 55 (3d Cir. 1992) (quotation marks omitted)). "In considering the motion, the Court 'does not resolve factual disputes or make credibility determinations.'" *Rhodes*, 302 F. Supp. 3d at 661 (quoting *Siegel Transfer, Inc. v. Carrier Express, Inc.*, 54 F.3d 1125, 1127 (3d Cir. 1995)). The inquiry at summary judgment is "whether the evidence presents a sufficient

disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson*, 477 U.S. at 251–52.

VII. DISCUSSION

A. The Promotional Claims Under the FCA

"The False Claims Act is meant 'to reach all types of fraud . . . that might result in financial loss to the Government.'" *Petratos*, 855 F.3d at 486 (quoting *Cook Cnty. v. U.S. ex rel. Chandler*, 538 U.S. 119, 129 (2003)). Relators bring their federal claims under 31 U.S.C. § 3729(a)(l)(A) and (B) of the FCA. (Second Am. Compl. ¶¶ 218–21.) The relevant provisions of the FCA impose civil liability on anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 372 (a)(l)(A), or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," 31 U.S.C. § 372 (a)(l)(B). Relators must prove the following elements: (1) falsity; (2) causation; (3) scienter; and (4) materiality.[5] *Petratos*, 855 F.3d at 487.

1. Falsity

There are two types of falsity under the FCA: "factual falsity" and "legal falsity." *United States ex rel. Druding v. Care Alts., Inc.*, 952 F.3d 89, 96–97 (3d Cir. 2020). A claim is "factually false" when the claimant misrepresents to the Government what goods or services it provided. *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011). A claim is "legally false" when the claimant misrepresents that he or she has complied with "statutory, regulatory, or contractual requirement[s]." *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 94 (3d Cir. 2018). In cases where a relator alleges the defendant caused the submission of false claims rather than submitting the claims itself, legal falsity

[5] Janssen does not move for summary judgment under the scienter element of the FCA. (Moving Br. at 12 n.5.)

nevertheless exists because the defendant "created and pursued a marketing scheme that it knew would, if successful, result in the submission by [others] of compliance certifications . . . that [the defendant] knew would be false." *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3d Cir. 2004). Here, two statutory requirements are relevant to Relators' allegations of legal falsity: (1) compliance under the Medicare statute; and (2) compliance with the AKS.[6]

First, under the Medicare statute, "no payment may be made . . . for any expenses incurred for items or services . . . [that] are not reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395w-102(e)(3); 42 U.S.C. § 1395y(a)(l)(A). Therefore, a claim is false when it "does not comply with statutory conditions for payment," such as the Medicare statutory requirement that the items and services claimed are "reasonable and necessary." *Petratos*, 855 F.3d at 487 (quoting 42 U.S.C. § 1395y(a)(1)(A)). *See also* 42 C.F.R. § 411.15(k)(l).

Second, a claim may be legally false where there is an underlying violation of the AKS. *Greenfield*, 880 F.3d at 95. The AKS prohibits "knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person . . . to refer an individual to a person for the furnishing . . . of any item or service for which payment may be made in whole or in part under a [f]ederal health care program." 42 U.S.C. § 1320a-7b(b)(2)(A). It is well-settled that "claims for payment made pursuant to illegal kickbacks are false under the [FCA]." *Greenfield*, 880 F.3d at 95 (quoting *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 52 (D. Mass. 2011)).[7]

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[6] Janssen does not address legal falsity under the Medicaid statute.

[7] In 2010, Congress amended the AKS to clarify existing law, expressly providing that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). "Although the amendment is not retroactive," plaintiffs may still bring an FCA case for claims submitted before 2010 because the amendment "clarif[ied], [but did] not alter, existing law that claims for payment made pursuant to illegal kickbacks are false under the [FCA]." *Greenfield*, 880 F.3d at 95 (citations omitted).

Here, Janssen contends Relators have insufficient evidence to prove falsity as to their claims based on the promotion of Prezista as "lipid friendly" or "lipid neutral." (Moving Br. at 13.) It argues that Relators failed to meet the second part of the "reasonable and necessary" analysis under *Petratos* because Relators have no evidence that "it was unreasonable and unnecessary for the 'individual doctor' to prescribe Prezista to the 'individual patient' based on the particular 'medical circumstance of the individual case.'" (Moving Br. at 14–15.) In *Petratos*, the Third Circuit explained that "the 'reasonable and necessary' determination is a process involving the FDA, CMS, and individual doctors." 855 F.3d at 488. Notwithstanding FDA approval, a claim must involve a drug that is "'reasonable and necessary for [the] *individual patient*' based on 'accepted standards of medical practice and the medical circumstances of the *individual case*.'" *Id.* (alteration and emphasis in original) (quoting Medicare Benefit Policy Manual, ch. 15, § 50.4.3). There are instances "when a drug treatment could be approved by the FDA and used for a medically accepted indication, but still not be 'reasonable and necessary'" for an individual patient. *Id.* Therefore, Relators would need to show that Prezista was not reasonable and necessary for patients with lipid conditions.

Relators point to evidence from which a jury could conclude that Janssen's OL promotion of Prezista's lipid profile misled physicians. Relators argue that Janssen made false assertions that Prezista was "lipid neutral" or "lipid friendly" (*i.e.*, the drug would not affect or increase a patient's cholesterol and triglyceride levels) even though the FDA-approved label for Prezista showed the drug caused a substantial increase in patients' lipids. Notably, Relators point to the anticipated expert testimony of Aaron E. Glatt, the HIV expert who opined that the "prescriptions for Prezista as a result of Janssen's false and misleading statements were not 'reasonable and necessary' for the treatment of patients who had concerning levels of lipids, triglycerides and/or cholesterol."

(Opp'n Br. 37; *see also* Ellerbe Decl., Ex. 75, Glatt Report ¶¶ 153–61.) According to Glatt, Janssen's OL promotion of Prezista misleadingly minimized the serious risk of cardiovascular disease for HIV/ AIDS patients.

Janssen contends that the label for Prezista does not include any warnings about the lipids or limitations on prescribing the drug to patients with lipid conditions, and Janssen notes that the FDA approved Prezista as a safe and effective HIV treatment after conducting clinical trials that considered potential lipid-related side effects. (Moving Br. at 15.) In essence, the parties dispute whether Prezista's label warned about any lipid-related side effects. (Relators' Response to DSMF at 11–12, ECF No. 287-1; Relators' Counterstatement of Material Facts ("CMF") at 11–12, ECF No. 287-2.) Contrary to Janssen's position, this constitutes a genuine issue of material fact as to Relators' FCA claims concerning Prezista's lipid profile. *Anderson*, 477 U.S. at 248. (Janssen's Response to CMF at 3, ECF No. 243.) The Court cannot resolve this factual dispute on summary judgment. *Rhodes*, 302 F. Supp. 3d at 661 (quoting *Siegel Transfer*, 54 F.3d at 1127).

Moreover, Relators advance a second legal falsity theory. For patients to receive reimbursement for a claim under a federal health care program, their doctors must certify that the claim complies with federal laws—including the AKS. When a claim is tainted by an AKS violation, it is automatically legally "false" under the FCA. *Greenfield*, 880 F.3d at 95. Therefore, once a violation of the AKS has been established, the first element of the FCA, falsity, has been met. For the reasons discussed in detail below, the Court separately finds that Relators have adduced sufficient evidence from which a reasonable jury could conclude that Janssen used its nationwide Speaker Programs to induce physicians to prescribe (or to reward them for prescribing) Prezista. Under either the OL promotion theory or the AKS violation theory, the Court concludes that Relators have raised sufficient questions of material fact to preclude summary judgement as

to whether Prezista claims for benefits made by patients with lipid conditions were false within the meaning of the FCA. *Rhodes*, 302 F. Supp. 3d at 661 (citing *Curley*, 298 F.3d at 276–77).[8]

2. Causation

Relators must also establish causation by showing that: (1) Janssen's promotional activities caused doctors to write OL prescriptions; and (2) these prescriptions were subsequently presented to the government for reimbursement. *See, e.g.*, *Celgene*, 226 F. Supp. 3d at 1037. In analyzing these causation elements, the Court applies the "substantial factor" test to determine whether presentment of the claims was a foreseeable and natural consequence of Janssen's conduct. *Id*. at 1037 (citing *United States ex rel. Colquitt v. Abbott Labs.*, Civ. No. 6-1769, 2016 WL 80000, at *6 (N.D. Tex. Jan. 7, 2016). *See also Schmidt*, 386 F.3d at 244 (applying ordinary causation principles from negligence law to determine responsibility under the FCA).

Janssen argues that Relators have no evidence that Janssen's OL promotion of Prezista and Intelence was a substantial factor in causing physicians to prescribe these medications for HIV patients. (Moving Br. at 17.) More specifically, Janssen argues that it is impossible for Relators to prove that the alleged OL promotional messages caused doctors to prescribe Prezista and Intelence without patient-specific evidence. (*Id.* at 17–18.) However, Relators are "not required to identify a particular false claim caused by [Janssen's] off-label promotion." *Celgene*, 226 F. Supp. 3d at 1041. In *Celgene*, the court did not require the relator to identify a specific claim but instead allowed the relator to "present[] 'sufficiently detailed circumstantial evidence' that such a claim was submitted" as a result of the pharmaceutical company's conduct. *Id.* at 1041.

[8] In passing, Janssen seeks relief as to the analogous state FCA claims. (Moving Br. at 13.) For the same reasons set forth above with respect to the federal FCA, the Court also finds there is sufficient evidence from which a reasonable jury could conclude that the Prezista claims for patients with lipid conditions were false under the analogous state false claims statutes.

Here, Relators argue that there is abundant evidence that Janssen's conduct was a substantial factor in causing physicians to prescribe Prezista and Intelence OL and that it was foreseeable false claims would result. (Opp'n Br. at 23.) They argue that the "vast body of evidence adduced by [them] demonstrates the top-down, widespread, and coordinated illegal promotional efforts by Janssen to boost sales of Prezista and Intelence." (Relators' CMF ¶¶ 16–17.) Relators identify evidence that Janssen trained and instructed its entire sales force to promote Prezista and Intelence OL. (*Id.* ¶¶ 24, 26, 36, 38–46, 52, 76, 81.) In addition, Relators point to evidence that Janssen's OL marketing campaign extended to its Speaker Programs because Janssen also promoted its OL messages through the physician-speakers. (*Id.* ¶ 51.) They also identify company documents that show Intelence and Prezista were being prescribed in the OL treatment-naïve markets, that Janssen tracked these OL sales, and that Janssen included the OL sales of its drugs into its sales forecasts. (CMF ¶¶ 32–35, 55, 82; Ellerbe Decl., Ex. 76, Sillup Report ¶ 66, ECF. No. 288–11.) For example, Relators' pharmaceutical marketing expert, George P. Sillup, reviewed substantial evidence in this case and explained that Janssen's management took the following actions to facilitate or encourage OL marketing: (1) developed unrealistic sales forecasts before it launched Prezista and Intelence; (2) instructed and trained its national sales force to promote Prezista and Intelence for OL uses; (3) encouraged physicians to write OL scripts through the Speaker Programs, where OL promotion took place; (4) sett compensation policies for sales staff that was based on an expectation of OL marketing; (5) encouraged sales staff to use unapproved studies when promoting Prezista and Intelence; and (6) failed to discipline its sales staff or managers for OL marketing. (Sillup Report ¶¶ 36–103.) He reached these conclusions by analyzing the FDA-approved labels for Prezista and Intelence, the eligible patient population, and Janssen's sales forecasts. (*Id.*) He relied on a highly technical process to determine that Janssen

created unrealistic sales forecasts for Prezista and Intelence, and he also analyzed documents tracking Prezista and Intelence sales to show that a significant proportion of sales were OL. (*Id.* ¶¶ 36–66.)

Moreover, Sillup also concluded that "Janssen's widespread and top-down campaign of OL marketing for Prezista and Intelence was a substantial factor in driving the volume of OL prescribing for Prezista and Intelence." (*Id.* ¶ 9.) He relied on the following to render this causation opinion: (1) guidance from courts, federal agencies, and the Office of the Inspector General that recognize OL marketing can cause physicians to write OL scripts; (2) academic and marketing literature that shows OL marketing influences prescribers; and (3) Janssen's internal and external marketing surveys showing that its OL marketing was causing physicians to write OL scripts. (*Id.* ¶¶ 104–134.) For the reasons discussed, the Court finds that a jury could reasonably conclude that Janssen's conduct caused physicians to prescribe Prezista and Intelence OL and that it was reasonably foreseeable that it would result in the submission of OL claims to the government for reimbursement.

3. Materiality

"A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the [FCA]." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 192 (2016). In other words, all FCA claims of legal falsity must also meet the FCA's materiality standard, "as falsity and materiality are distinct requirements . . . ." *Greenfield*, 880 F.3d at 98 n.8. The FCA "defines 'material' to mean 'having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.'" *Escobar*, 579 U.S. at 183 (quoting 31 U.S.C. § 3729(b)(4)). *See also United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746,

761 (3d Cir. 2017). Accordingly, "materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'" *Escobar*, 579 U.S. at 193 (alteration in original) (citation omitted). The FCA's "materiality standard is demanding." *Id.* at 194. In *Escobar*, the Supreme Court identified the following nonexclusive factors to determine materiality: (i) whether compliance with a particular statute is a "condition of payment"; (ii) whether the violation is substantial and goes to "the essence of the bargain" or is "minor [and] insubstantial"; and (iii) whether the government pays or declines to pay a "particular claim" or "particular type of claim" when it has "actual knowledge that certain requirements were violated." *Id.* at 193 n.5, 194–95. *See United States ex rel. Gohil v. Sanofi U.S. Servs. Inc.*, Civ. No. 02-2964, 2020 WL 6682483 (E.D. Pa. Nov. 12, 2020). Since these factors are nonexclusive, courts may take into consideration other factors when determining materiality. *Escobar*, 579 U.S. at 194–95; *United States ex rel. Escobar v. United Health Servs., Inc.*, 842 F.3d 103, 109 (1st Cir. 2016) (acknowledging, on remand, that "[*Escobar*] makes clear that courts are to conduct a holistic approach to determining materiality in connection with a payment decision").

Janssen argues that "Relators have insufficient evidence to prove that any of Janssen's four alleged promotional messages were material to the government's decision to reimburse a Prezista or Intelence prescription." (Moving Br. at 18.) Here, Relators allege that Janssen made the following OL promotions: (1) Prezista as "lipid neutral" or "lipid friendly" and appropriate for patients with lipid conditions; (2) Prezista for treatment-naïve patients (patients who previously had not been prescribed HIV medications to treat their HIV) before it was FDA-approved for that patient population in October 2008; (3) Intelence for once-daily dosing even though it was only approved by the FDA for twice-daily dosing; and (4) Intelence for treatment-naïve patients even though it was never approved by FDA for those patients. Relators allege that claims for prescriptions of Prezista and Intelence were false because they were neither for medically accepted indications nor

reasonable and necessary. *See, e.g.*, *Celgene*, 226 F. Supp. 3d at 1049 (explaining that a medically accepted indication is an explicit condition of payment under Medicare Part D); *United States ex rel. Bergman v. Abbott Labs.*, 995 F. Supp. 2d 357, 367 (E.D. Pa. 2014) (explaining that prescriptions for uses that are "'not reasonable and necessary for treatment,' make those uses ineligible for reimbursement under Medicare and Medicaid regulations"). After reviewing the record, the Court finds that Relators have identified evidence in the form of expert testimony from which a jury could conclude that Janssen's conduct violated an express condition of payment, which would tend to show that it was material to the Government's decision to reimburse the claim. *Escobar*, 579 U.S. at 193. In short, a genuine dispute of material fact exists as to whether the OL promotions were material to the payment decisions at issue here. (Ellerbe Decl. Ex. 82, Schafermeyer Report ¶¶34–59, ECF No. 288-12.)

B. Speaker Claims Under the AKS

The AKS prohibits "knowingly and willfully" offering or paying any "remuneration" to induce prescriptions that may later be reimbursed under a federal health care program. 42 U.S.C. § 1320a-7b(b). Relators allege that Janssen violated the AKS by paying physicians to prescribe Prezista and Intelence. To establish that Janssen violated the AKS, Relators must prove the following: (1) the alleged schemes involved "remuneration"; (ii) at least one purpose of the schemes was to "induce" doctors to prescribe more Prezista and Intelence; and (iii) Janssen possessed the requisite scienter. *Id.* In this instance, payments to physicians violate the AKS if even "one purpose" of the payments was to induce or reward the speakers to prescribe Prezista or Intelence. *See United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985); *Purcell v. Gilead Scis., Inc.*, 439 F. Supp. 3d 388, 398 (E.D. Pa. 2020) ("It is sufficient if at least 'one purpose of the

payment was to induce' Medicare purchases . . . ."); *United States ex rel. Judd v. Quest Diagnostics Inc.*, Civ. No. 10-4914, 2014 WL 2435659, at *12 n.11 (D.N.J. May 30, 2014) (same).

There is a genuine issue of material fact with respect to the first element of the AKS: whether compensation under the Speaker Programs constitutes "remuneration" under the Act. The AKS defines remuneration as "transfers of items or services for free or for other than fair market value." 42 U.S.C. § 1320a-7a(i)(6). Courts generally interpret remuneration "expansively to include anything of value in any form whatsoever." *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 805 (S.D.N.Y. 2017) (internal quotation marks omitted), *rev'd on other grounds*, 899 F.3d 163 (2d Cir. 2018). Here, Relators highlight that Janssen paid hundreds of physicians a significant amount of money to give thousands of speeches over the relevant nine-year period. (Relators' CMF ¶¶ 86–87.) Janssen also paid physicians to attend training sessions and paid for their hotels, meals, and travel expenses. (*Id.* ¶¶ 89–91.) Many speeches were held at expensive venues, including thousands of speeches at high-end restaurants. (*Id.* ¶¶ 114–15.) Therefore, a jury could find that the Speaker Programs involved "transfers of items or services for free or for other than fair market value." 42 U.S.C. § 1320a-7a(i)(6).

There also exists a genuine dispute of material fact as to the second element of the AKS: whether one purpose of the Speaker Programs was to induce physicians to prescribe Prezista and Intelence. Relators point to sworn deposition testimony of seven current and former Janssen employees who testified that the Speaker Programs focused, in significant part, on inducing and rewarding prescriptions. (Relators' CMF ¶¶ 19–21, 84.) Relators explain that Janssen tracked the prescriptions of the paid speakers *and* all attendees (some of whom were also paid speakers) to monitor the return on investment of its Speaker Programs. (*Id.* ¶¶ 95–104.) There is evidence that hundreds of physicians attended the same speech multiple times, and the speeches were highly

repetitive and rudimentary for the doctors attending. (*Id.* ¶¶ 112–13, 117–19; Ellerbe Decl., Ex. 75, Glatt Report ¶¶ 183–98.) Relators also point to evidence that the information presented during the Speaker Programs was incomplete, inaccurate, and misleading, and that the OL information about Prezista and Intelence was regularly presented by the highest paid speakers. (Relators' CMF ¶¶ 47–51, 110–11.) Relators point to the analyses of their expert economist to show that speakers continued to prescribe Prezista and Intelence once they started receiving payment and that speakers were more likely than non-speakers to prescribe Prezista and Intelence. (Ellerbe Decl., Ex. 73, Shaked Report ¶¶ 69–97.) Additionally, there is evidence that Janssen's compliance department had little oversight over the Speaker Programs; instead, the Speaker Programs were controlled by Janssen's sale representatives (who were incentivized to increase sales) and Janssen's marketing department. (Relators' CMF ¶¶ 120–22.) For all of these reasons, viewing the facts in a light most favorable to Relators, the Court finds that a reasonable jury could conclude that one purpose of Janssen's Speaker Programs was to induce the physicians to prescribe more Prezista and Intelence.

VIII. CONCLUSION

The Court concludes that Relators have identified evidence raising material facts in dispute on every issue raised by Janssen. As a result, the Court will deny Janssen's motion for summary judgment. An appropriate Order will accompany this Opinion.

Date: December 21, 2021

s/ Zahid N. Quraishi
ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE